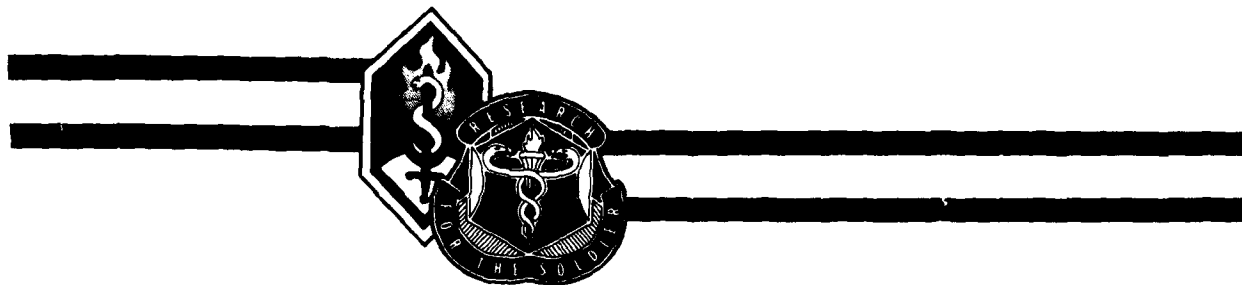


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Extended-Wear Soft and Rigid Contact Lenses: Operational Evaluation Among Army Aviators

By

William G. Bachman

Sensory Research Division

September 1988

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Background

With increasing technological complexity in the Army aviation environment, the role of vision becomes more and more important. Aviation systems incorporating sophisticated electro-optical displays frequently are designed without adequate provision for use by personnel wearing spectacles. An example of this is the Integrated Helmet and Display Sighting System (IHADSS) for the AH-64 Apache Attack Helicopter (see Figure 1). This system displays both aircraft symbology and weapons control information, as well as video from the infrared sensor for night flying. The position of the combiner lens at a close vertex distance in front of the right eye causes standard issue aviator spectacles to be incompatible with



Figure 1. Integrated Helmet and Display Sighting System.

the system. In addition, new protective gas masks are being developed that are incompatible with spectacles or corrective inserts. The use of contact lenses could offer a solution to these problems.

Army aviators must meet stringent vision standards for acceptance into the aviation program. However, at least two factors can lead to their being required to wear corrective lenses subsequent to acceptance. First, there is the tendency of some individuals to develop myopia as they mature. Second, during periods of high manpower demand, it is common for vision standards to be relaxed to increase the available "pool" of eligible candidates for aviation training. Currently, approximately 18 percent of all Army aviators wear corrective lenses.

A method or approach often used to interface a soldier who has a refractive error with an optical system is to incorporate a dioptric adjustment into the instrument. This allows the user to dial the appropriate compensating lenses for his or her refractive error. This is similar to what is done in binoculars. However, associated with this approach is an increase in cost and weight. Another problem unique with a monocular system, such as that in the Apache helicopter, is only one eye can be compensated while the other remains uncorrected. A third and very serious shortcoming to this method is it only permits the optical correction of spherical or near spherical errors, offering no solution to those with astigmatic refractive errors. The use of contact lenses by aircrew personnel required to wear corrective lenses offers one potential solution to the compatibility problem.

As with treatment modalities, contact lenses offer both advantages and disadvantages to the Army aviator when compared to wearing spectacles.

Advantages:

1. Enhanced integration with optical devices.
2. No spectacle frame to block field-of-view.
3. No frame discomfort under the helmet.
4. No slipping or dislodging when running, jumping, etc.
5. No sweat streaking or "fogging up."
6. No "ghosts" or reflected images.

Disadvantages:

1. Cannot be tolerated by all personnel.

2. Will not correct every type of vision problem.
3. Vision may fluctuate periodically.
4. Cleaning and disinfection may be difficult in a field environment.
5. Wearers must carry lens-related solutions and supplies.
6. Additional visits to the eye clinic are required.

A generalized assessment of the requirements of an Army pilot reveals that he would be expected to fly on short notice, for extended periods, and in a dirty environment. All these factors would seem to preclude wearing contact lenses in a daily wear mode, where frequent handling would be required. Extended wear of contact lenses offers a way of overcoming these unique requirements. In order to minimize physiological risks and interference with the pilot's performance of duties, a 7-day extended wear schedule should be suitable. A 7-day schedule should permit most military operations to be accomplished without interference.

Literature review

An early study by Crosley, Braun, and Bailey (1974) of daily wear soft contact lenses in the aviation environment was performed just subsequent to the Food and Drug Administration (FDA) approval of these lenses for public use. A problem involving earlier hard contact lenses was wearer susceptibility to foreign bodies. It was obvious Army aviators flying helicopters frequently would be exposed to dusty environments. One of the conclusions reached in this study was large diameter soft lenses eliminated foreign body involvement. However, they did cause unacceptable variability in visual acuity. A study by Polishuk and Raz (1975) of Israeli civilian and military pilots addressed the use of hydrophilic lenses under varying conditions of altitude, oxygen level, humidity, and lighting. This study concluded dust and dirt were not a problem, that variable visual acuity meant not every ametropic pilot was a candidate for soft contact lenses, and that many aviation personnel would benefit from the use of these lenses.

Directing their effort toward low atmospheric conditions, Eng, Rasco, and Marano (1978) studied the Soflens in a hypobaric chamber. Subjects fitted with these lenses were exposed to varying simulated altitudes up to 30,000 feet. It was concluded the low atmospheric pressure at high altitude in itself did not affect the wearability of these soft lenses. Low humidity at high altitudes was reported to cause problems for flight attendants wearing soft contact lenses because of dehydration (Eng, 1979). The majority of flight

attendants queried relied upon artificial tears to alleviate this problem.

Nilsson and Rengstorff (1979) studied five Swedish Air Force pilots who wore extended-wear soft lenses for more than 3 years without complications. Four were fighter pilots while one flew helicopters. There were no circumstances in which problems were caused by wearing lenses in flight. All subject pilots reported better central and peripheral vision, as well as greater ease in using head-up displays. The authors further state the wearers encountered no problems with gravity up to 6 Gs, atmospheric pressure changes equivalent to those at 75,000 feet, low cockpit humidity, or target acquisition day or night.

The Canadian Forces have been interested in the use of contact lenses for aircrew for several years. During the period 1977 to 1981, studies (Forgie, 1981) were conducted on lens performance associated primarily with high speed, high altitude flight. Subjects wearing soft lenses were placed in a centrifuge and exposed to as much as +5.1 G's at eye level. The amount of lens displacement between subjects was highly variable and affected by blinking, facial tensing, and lid tightness, but in no subject was the slippage sufficient to leave the pupil uncovered by the optical zone of the lens. In hypobaric chamber studies at both 25,000 feet for 2.5 hours and 9,000 feet for 6 hours, some of the subjects experienced minor discomfort and showed some tear film debris. However, Forgie (1981) states "in no case was there any problem sufficient to potentially interfere significantly with aircraft control."

In the Federal Republic of Germany, restrictions placed upon the wearing of contact lenses by commercial pilots led to a study by Draeger (1981) which addressed the major objections to their use. These "official" objections were (1) displacement under acceleration, (2) gas bubble formation with sudden drops in atmospheric pressure, and (3) mechanical irritation at high altitude due to low humidity. The author found that (1) high g-load does not affect the position of the lenses or visual acuity; (2) modern, well-fitted lenses do not cause problems of gas bubble formation; and (3) low humidity does not cause significant conjunctival or corneal irritation.

An epidemiological study of civilian aviation visual deficiencies (Dille and Booze, 1982) reports that in 1979, 42 percent of all active civil airmen required corrective lenses. Of these, 6 percent were known to wear contact lenses when they flew. A review of all civil aviation accident data failed to demonstrate any change in the rate of accident involvement for contact lens wearers compared to that of the normal population.

British researchers (Brennan and Girvin, 1984) studied officer aircrew fit with medium and high water content extended-wear lenses.

During the course of the study, the subjects were exposed to hypoxia, rapid decompression, pressure breathing, vibration, climatic excesses, G forces, and the prolonged wearing of an aircraft respirator. Their visual performance wearing contact lenses under ground testing conditions did not differ significantly from the control values, either when wearing corrective flying spectacles or contact lenses when not under stress. Braithwaite (1983) followed British Army aviators wearing contact lenses for flight duty. The use of contact lenses is authorized if "aircrew demonstrate tolerance for contact lenses by wearing for 16 hours a day over a period of 6 months on ground duty." Contact lens wearers are required to carry standard aviation spectacles when performing flying duties. This group consisted of seven pilots authorized to fly while wearing contact lenses. They ranged in age from 31 to 54, and had worn either hard, soft, or extended wear lenses for 1 to 12 years. Time flown with contact lenses ranged from 10 to 1100 hours. Braithwaite says "suitability of contact lens use must depend upon the individual circumstances of use, extensive time spent in the field is not compatible with the use of contact lenses, and soft lenses are generally better tolerated than hard lenses."

Tredici and Flynn (1987) have used contact lenses to visually rehabilitate aircrew members of the U. S. Air Force. These were pilots, navigators, and other aircrew who presented such defects as keratoconus, aphakia, and anisometropia. Contact lenses were the only mechanism by which these individuals could be returned to flight status. Hard lenses were used in 70 percent of the cases and soft lenses in 30 percent.

Materials and methods

Subjects

The use of contact lenses by Army aircrews when flying is expressly prohibited by Army Regulation 40-63, Ophthalmic Services (October 1983), and Army Regulation 40-501, Standards of Medical Fitness (December 1983). A waiver of policy relating to the use of contact lenses for selected aviators was sought from and approved by The Office of The Surgeon General. This waiver covered the use of extended-wear lenses worn by pilots flying at Fort Rucker, Alabama, while participating in the present investigation. In addition, a small number of pilots were waived to fly while wearing soft extended-wear lenses at Fort Hood, Texas.

The aviators who volunteered to participate in this study were male officers or warrant officers ranging in age from 21 to 42, with a mean age of 33. All were on active flight status. The health records of eligible volunteers were screened to eliminate conditions which would medically contraindicate their participation as a subject. These included, but were not limited to, acute and/or subacute inflammations of the anterior segment of the eye; any

disease affecting the cornea, conjunctiva or sclera; corneal hypoesthesia; low tear breakup time; insufficient lacrimation; a requirement to take certain medications, such as diuretics and decongestants; or a history of moderate-to-severe allergy. No aviator was disqualified for any of the above conditions. Eligible pilots were briefed on the study. It was emphasized they would not be allowed to retain the contact lenses after the study was terminated, because of regulation restrictions. All were required to have, to the best of their knowledge, 7 months or more remaining on their current assignment.

Aircraft flown

All subjects were helicopter pilots, except one who flew the U-21 fixed-wing aircraft. See Table 1 for a listing of the types of aircraft flown. Some subjects flew as many as three different types of aircraft over the course of the study.

Table 1.
Types of aircraft flown

<u>Aircraft</u>	<u>Category</u>
UH-1 (Iroquois)	Utility helicopter
OH-58 (Kiowa)	Observation helicopter
UH-60 (Blackhawk)	Utility helicopter
AH-1 (Cobra)	Attack helicopter
AH-64 (Apache)	Attack helicopter
U-21 (Ute)	Utility aircraft

Personnel and facilities (medical)

All subjects (34) at Fort Rucker were fit by the same optometrist in the Sensory Research Division of the U. S. Army Aeromedical Research Laboratory. An additional 10 subjects were fit by three different optometrists at Darnall Army Community Hospital at Fort Hood, Texas.

Lenses

Six different extended-wear contact lenses, four soft and two rigid, were used in this study. They represent a cross section of the various lenses available from U. S. manufacturers, and it was anticipated they would provide sufficient fitting latitude to adequately serve the aviation population. See Table 2 for a listing of the lenses used. The rigid lenses were fit under an FDA

investigational protocol. All lenses were disinfected chemically as per manufacturer's instructions.

Table 2.
Contact lenses used

Lens	Manufacturer
Permalens XL	Coopervision, Inc.
CSI T	Sola-Syntex, Inc.
Hydrocurve II	Barnes-Hind, Inc.
Hydrocurve Toric	Barnes-Hind, Inc.
Paraperm EW I	Paragon Optical, Inc.
Paraperm EW II	Paragon Optical, Inc.

Procedures

The initial examination included visual acuity, objective and subjective refraction, keratometry, aesthesiometry, Shirmer tear testing, tear breakup time, tonometry, biomicroscopy, and photography. Volunteers then were fit with the contact lens which provided the best visual acuity (at least 20/25 each eye), stability, and comfort. Following fitting, subjects were given instructions by a technician concerning lens insertion, removal, and care. Followup examinations were performed at 24 hours, 7 days, and every 30 days thereafter. Additional clinic visits, if necessary, were initiated by the subject or practitioner. Regardless of type, the contact lenses were worn without removal for 7 (+/- 1) days. On the seventh day, the lenses were removed 2 hours before bedtime, cleaned thoroughly, and stored properly until reinsertion the following morning. At the end of 4 months of wear or earlier, all soft extended-wear lenses were replaced with new lenses to minimize buildup of deposits on the lenses. Complete data were recorded during each vision exam. Standardized data collection forms were used and all information then was transferred to a computer database. Self-administered questionnaires were used to obtain subjective information from participants at the end of their participation in the study (6-24 months of cumulative wear). These questionnaires addressed user acceptability, job performance impact, and problems encountered.

Results and discussion

A total of 44 pilots participated in this study. Twenty-seven wore extended-wear soft lenses (17 at Fort Rucker and 10 at Fort Hood). An additional 17 pilots wore extended-wear hard gas permeable lenses at Fort Rucker.

The mean uncorrected visual acuity (VA) was 20/47 (range 20/15 to 20/200). Figure 2 shows the spherical refractive error distribution of all eyes. The mean spherical error was -0.69 (range -2.50 to +0.62). Figure 3 shows the cylindrical refractive error distribution of all eyes. The mean cylindrical error was -0.51 (range -2.25 to 0.00).

All subjects received an intraocular pressure test during the initial exam and were within normal limits. Shirmer tear testing was accomplished on all subjects. The mean finding for the subject pilots was 18.6 mm/5 min. Tear breakup time also was measured as a reflection of the stability of the tear film. The mean breakup time was 23.1 seconds per eye with a range from 10 to 50 seconds. The mean keratometry reading prior to contact lens fitting was 43.18 diopters (40.00 to 46.50) in the flat meridian and 43.66 diopters (40.37 to 48.25) in the steep meridian.

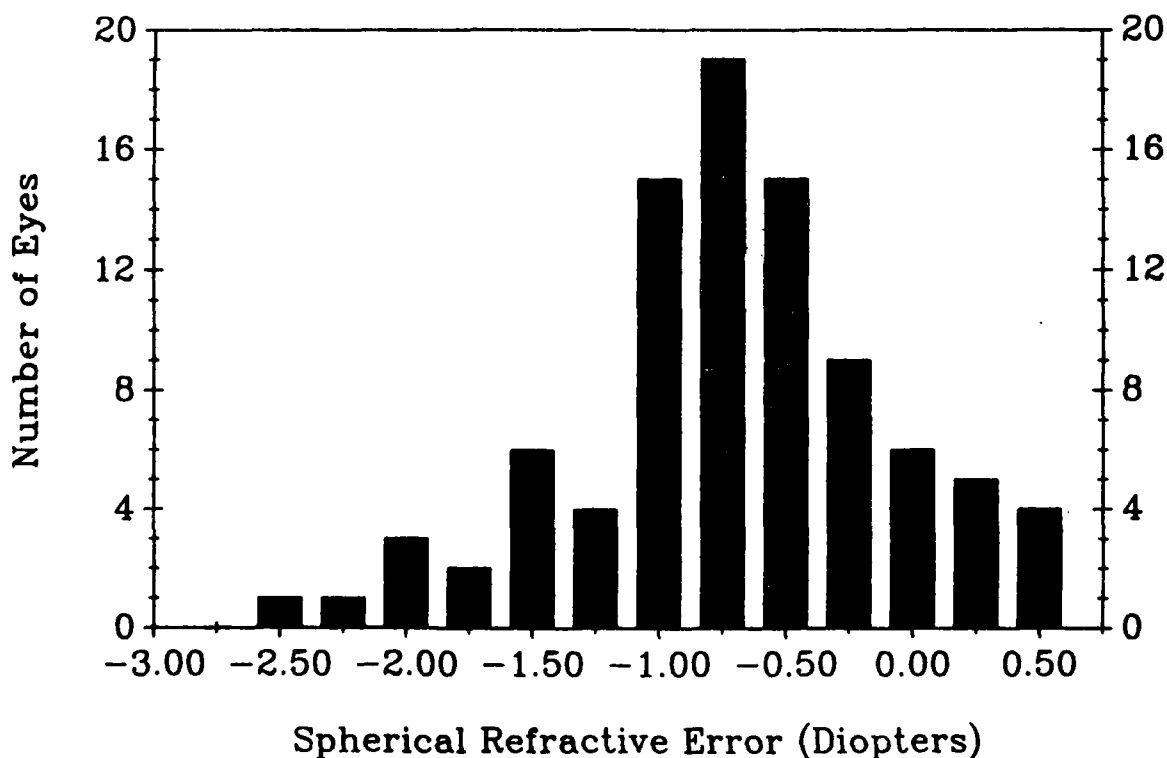


Figure 2. Distribution of spherical refractive errors.

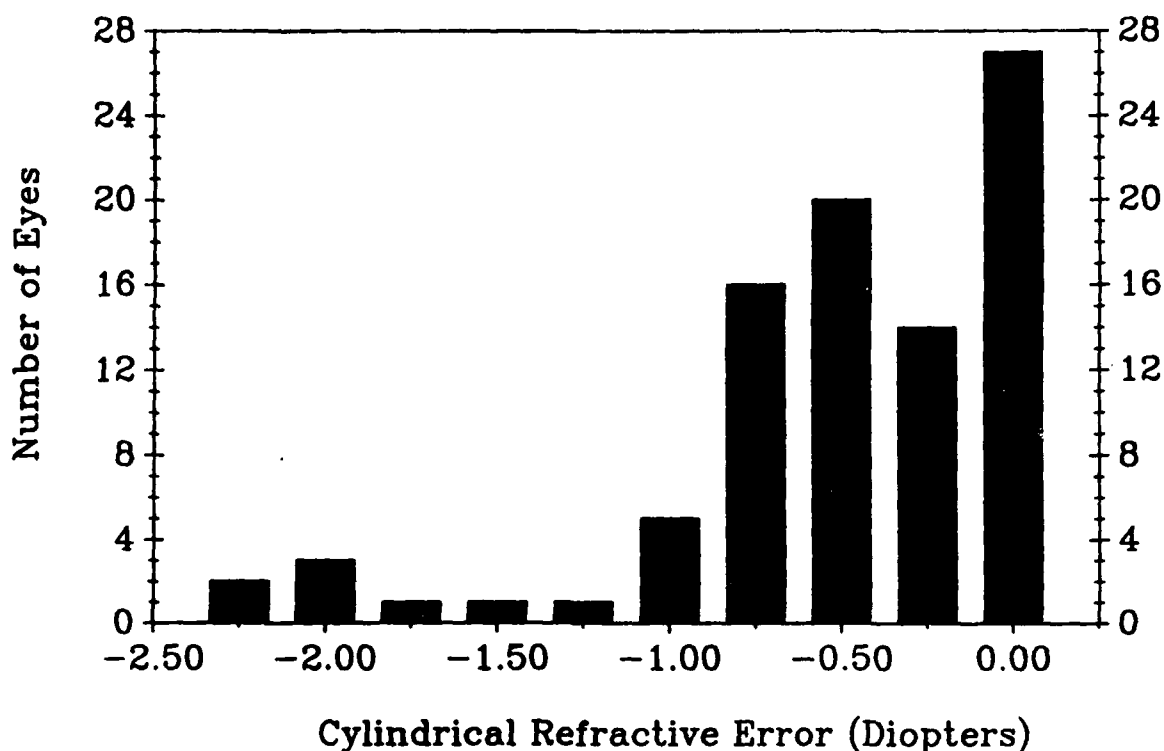


Figure 3. Distribution of cylindrical refractive errors.

The mean best corrected visual acuity (obtained subjectively through the phoropter) was 20/18, with a very tight range from 20/15 to 20/20. This is a reflection of the population, who have had to meet very stringent visual requirements to pass flight physicals. The mean best corrected visual acuity with contact lenses was 20/19, again with a very tight range from 20/10 to 20/25. No subject would have been allowed into the study if 20/25 vision monocularly had not been achieved with contact lenses.

The distribution of the different lens types fit appears in Table 3. One subject wore a lens in one eye only, and one subject wore a spherical lens in one eye and a toric lens in the other. Mean contact lens spherical power was -0.77 and ranged from -2.50 to 0.00.

Summary data from biomicroscopy examinations appear in Table 4. Although each subject received a biomicroscopic evaluation during each clinic visit, only data from the initial and 6-month examinations are presented. No data from the Fort Hood aviators or from subjects who withdrew from the study (see below) are included. For the subject fit monocularly, only one eye is represented. Classification codes used were those recommended by the Food and Drug Administration for clinical investigations.

Table 3.
Percentage of lenses fit

Lens used	No. of eyes fit	Percent
Hydrocurve II	19	22
Permalens XL	19	22
Hydrocurve Toric	5	6
CSI T	10	11
Peraperm EW I	20	23
Peraperm EW II	14	16

As can be seen from Table 4, the percentage of eyes exhibiting slight edema was very small at the 6-month point. As expected, corneal edema was nonexistent prior to contact lens fitting. The same holds true for corneal staining which was not found at the initial exam and was present in 4 percent of eyes at 6 months.

Minimal vascularization of the cornea was found in 9 percent of eyes prior to contact lens fitting. This increased to 35 percent of eyes at the 6-month point. It should be noted we used a very stringent criterion in reporting vascularization. Other researchers (Zucarro, Thayer, and Poland, 1985; Nilson and Persson, 1986) tend to regard any vessel ingrowth less than 2 mm as not significant. Ingrowth greater than 2 mm did not occur in this study.

Mild congestion and dilation of the limbal vessels was observed in 36 percent of eyes at the 6-month examination, as opposed to 4 percent of eyes initially (Table 4). Contact lenses can be a factor in causing injection due to increased edema, mechanical irritation, and sensitivity reactions to the solutions used in their storage and disinfection. However, transitory injection often is caused by local irritants such as dust, wind, smoke, fumes, and exposure to bright light. All of these irritants are present daily in the environment in which Army pilots function.

In accordance with accepted clinical practice and the terms of the research protocol, contact lens wear was suspended temporarily when ocular complications developed. Six pilots were temporarily discontinued from contact lens wear. One individual was suspended twice and one individual three times. No pilot was grounded for contact lens related complications. Table 5 shows the cause and length of suspension for each occurrence. The most common cause of suspension was conjunctivitis, which occurred three times, twice with the same individual. Foreign body involvement occurred two times, as did abrasion. There was one case of meibomitis and one incident of facial trauma from dog bite which led to suspension of lens wear. The length of suspensions ranged from 4 to 19 days with the average suspension lasting 9 days.

Table 4.
Percentage of eyes exhibiting biomicroscopy classifications

Classification	Initial (N=55)	6-month (N=55)
<u>Edema</u>		
None	100 %	96 %
Slight	--	4 %
Moderate	--	--
Vertical striae	--	--
<u>Staining</u>		
None	100 %	96 %
Minimal peripheral	--	4 %
Superficial punctate	--	--
Abrasions	--	--
<u>Vascularization</u>		
None	91 %	65 %
Minimal ingrowth, < 2 mm	9 %	35 %
Extensive ingrowth, > 2 mm	--	--
<u>Injection</u>		
None	96 %	64 %
Mild congestion	4 %	36 %
Severe congestion	--	--

Table 5.
Temporary suspensions

Subject	Duration (days)	Reason
B. D.	4	Abrasion
J. L.	5	Conjunctivitis
A. L.	5	Meibomitis
B. H.	10	Abrasion
T. B.	4	Foreign body
T. B.	19	Facial trauma
A. B.	6	Conjunctivitis
A. B.	16	Conjunctivitis
A. B.	12	Foreign body

No subject was removed from the study for medically related problems. Six pilots withdrew themselves for discomfort or dissatisfaction with acuity. This resulted in a 14 percent loss or

an overall 86 percent success rate (see Table 6). Two of 27 soft lens subjects withdrew, both for dissatisfaction with acuity, leaving a 93 percent success rate for this group. Four of 17 rigid lens subjects withdrew, all for discomfort, leaving a 76 percent success rate for this group. None of those who were temporarily suspended were among those who withdrew. Comparable rates were reported by Zantos, Davies, and Reule (1982) -- 88 percent for a low water soft lens; Nilsson and Persson (1986) -- 92 percent for a high water soft lens; and Henry, Bennett, and Forest (1987) -- 83 percent for rigid gas permeable lenses.

Table 6.
Success rate

Number of pilots fitted -----	44
Number of pilots withdrawn for medical reasons -----	0
Number of pilots withdrawn for dissatisfaction with lenses -----	6
Number of pilots completing 6 or more months of extended wear -----	38
Success rate -----	86 %

Thirty-five of the subjects completed a questionnaire at the end of their participation in the study, following 6-24 months of contact lens wear. This was done to obtain information concerning difficulties encountered while they wore their lenses, as well as job performance impact. This questionnaire addressed specific situations experienced by the subjects. These situations pertained to job or task performance, environmental problems, operational settings, and use or care of contact lenses. It is worth noting that this group of pilots had a great deal of aviation experience. Total flying time prior to contact lens wear ranged from 100 hours to 6700 hours, with a mean of 2136 hours. Total flying time with contact lenses ranged from 5 hours to 1060 hours with a mean of 294 hours.

The participants in this study were asked to respond to the operational impact of wearing contact lenses while in flight. It should be understood that for the majority of flights, two pilots are found in the typical Army aircraft. This is not always mandatory, but is the norm rather than the exception. As can be seen from Table 7, contact lens problems rarely caused a pilot to reschedule or cancel flights. Subjects were even less likely to have to deviate from their flight plan. Twenty percent of the pilots did have to remove a contact lens during flight and this or other problems required a slightly higher percentage to turn over control of the aircraft to their colleagues. A much higher number (40 percent) had occasion to use rewetting eye drops during flight.

Table 7.
Operational impact of contact lenses
(N=35)

	Yes	No
Reschedule or cancel flights	11 %	89 %
Deviate from flight plan	3 %	97 %
Turn over controls in flight	23 %	77 %
Remove a lens in flight	20 %	80 %
Use eye drops in flight	40 %	60 %

Subjects were queried as to whether they encountered any discomfort attributable to a particular aircraft while wearing contact lenses. Sixty percent reported no difficulties. Forty percent did report occasional discomfort or irritation and these fell into two categories that were specific to aircraft types. For those aircraft that are flown with the canopy closed and provided with an environmental control unit (attack helicopters), the drying effect of forced air through the vents was a problem for some aviators. The other category involved utility aircraft which often are flown with doors either open or removed in hot weather. Five pilots complained of occasional dust irritation under these circumstances (Table 8). No pilot in either category was forced to remove a contact lens to alleviate the problem.

The subject aviators were asked to report their expectations for contact lens use if they were required to deploy and operate in the field for an extended period. Fifty-seven percent felt there

Table 8.
Discomfort related to aircraft
(N=35)

None	60 %
Drying from environmental control vents	25 %
Dust irritation with windows/doors open	15 %

would be no difference in the field environment than being able to "go home" after work. Fourteen percent had no opinion, while 29 percent felt hygiene would be an obstacle to overcome for successful wear of their lenses. However, only three percent responded negatively when asked if they expected to have the time and facilities to care for contact lenses in that environment.

Also elicited from each respondent was a subjective relative performance comparison concerning several operations

unique to flying in the military environment. Subjects were asked to indicate which was better for each task -- contact lenses or spectacles. Table 9 lists the preference patterns. All are based on an N of 35 except for the final two categories. Nine subjects did not experience night flight with night vision imaging systems and over one-half (19) had no occasion to don protective masks and clothing for flight. It readily is apparent that in all categories involving flight, a large majority (83 percent or greater) felt contact lenses were preferable to spectacles. Most of the anecdotal comments explaining these preferences referred to the following: no frame discomfort under the helmet caused by temples, better seal with the ear cups for the same reason, no sweat

Table 9.
Subjective performance comparison

Operational task	Contact lenses better	Spectacles better	About the same
Preflight	68 %	9 %	23 %
Takeoffs	83 %	0 %	17 %
Routine flight	83 %	0 %	17 %
Low level flight	89 %	0 %	11 %
Instrument flight	83 %	0 %	17 %
Night vision goggle flight	88 %	8 %	4 %
Flight with protective masks	100 %	0 %	0 %

streaking, and better field-of-view. Contact lenses were preferred by a smaller majority (68 percent) for preflight. This may be related to the fact that part of this task is performed out of the aircraft without the helmet. It is worth noting although only 16 respondents wore protective masks during this study, 100 percent felt contact lenses were preferable to optical inserts.

Conclusions

This is the first major field evaluation of contact lenses in U.S. Army aviation. The results of this study eventually will represent part of a larger data base concerning the use of contact lenses in the aviation environment, as well as other operational settings, environmental factors, and military occupations.

Success rate estimates appear to have validity in this study, since no subject was rejected because of amount or type of refractive error. Bachman et al. (1987) in a study of contact lenses in the armor environment, prescreened volunteers and rejected those who manifested more than moderate amounts of astigmatism. Prescreening can lead to concerns when attempting to generalize results. As previously stated, no subject was found unsuitable for

medical reasons in this study; therefore, each subject who volunteered was fit with contact lenses. This was possible primarily because of the wide range of lens types and parameters available.

Subjectively, extended wear of contact lenses was judged uniformly favorable in its effect on job performance. However, it is also apparent there will be occasions when contact lens wearing aviators will have to remove lenses or administer drops while flying. A percentage of pilots, however small, will be fitting or wearing failures. In addition, there will be periods of suspension from contact lens wear when pilots must use their spectacles.

This study did not address the support or logistical issues inherent in contact lens wear and care. Issue and resupply of lenses, cases, and solutions are critical to safe and effective contact lens use. Periodic examinations and access to clinicians knowledgeable in contact lens care also are essential. At the present time Army Regulation 40-63 states that the prescribing and issuing of contact lenses are authorized only at those military treatment facilities that have an optometrist or ophthalmologist competent in contact lens fitting assigned and where adequate diagnostic, inspection, and modification equipment is available. Providing contact lenses for Army aviators almost certainly would require additional medical personnel and logistical support.

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Appendix A

List of contact lens manufacturers

Barnes-Hind, Incorporated
8006 Engineer Road
San Diego, CA 92111

CooperVision, Incorporated
3000 Winton Road, South
Rochester, NY 14623

Sola-Syntex
P.O. Box 39600
Phoenix, AZ 85069

Paragon Optical
947 East Impala Avenue
Mesa, AZ 85204

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Fort Detrick, Frederick,
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Alexandria, VA 22333

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and Doctrine Command
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Fort Monroe, VA 23651

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TMC #22, SAAF
Fort Bragg, NC 28305

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Eglin Air Force Base, FL 32542

U.S. Army Missile Command
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Information Center
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Redstone Arsenal, AL 35898-5241

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John A. Dellinger,
Southwest Research Institute
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Aviation Life Support Equipment
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4300 Goodfellow Blvd.
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